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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,690	08/05/2002	Neil J. Rowley	PA-9948	3740
22840	7590	11/09/2004	EXAMINER	
AMERSHAM BIOSCIENCES PATENT DEPARTMENT 800 CENTENNIAL AVENUE PISCATAWAY, NJ 08855			HARTLEY, MICHAEL G	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 11/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/069,690

Applicant(s)

ROWLEY ET AL.

Examiner

Michael G. Hartley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Response to Amendment

The preliminary amendment filed 30 September 2004 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Felder (US 5,132,409) in view of either one of Schott Glaswerke (DE 29609958) or Walther (US 6,200,658), for the reasons set forth in the office action mailed 6/29/2004.

Applicant's arguments filed 9/30/2004 have been fully considered but they are not persuasive.

Applicant asserts that Felder provides no general teaching of metal complex contrast agent compositions in vials because Felder only discloses specific macrocyclic gadolinium metal complexes in vials, as exemplified in examples 14-19.

The relevance of this assertion is unclear. Clearly, Felder discloses metal (Gd) complex (macrocyclic chelates) in vials as contrast agents.

Applicant asserts that Felder's general silence on vials shows that vials are not regarded as a significant part of the invention of Felder. Applicant alleges that many of the compositions taught by Felder would presumably not even be suitable for vials.

Again, the relevance of this is not seen. Felder does disclose contrast agents in vials. The secondary references provide the significance of contrast agents and other pharmaceuticals in vials. The allegation that many of the compositions taught by Felder would not be suitable for a vial is unseen. Almost any composition would be suitable for a vial. The word "vial" is a broad term, meaning, a small container, as defined by a dictionary. Clearly, any of the compositions disclosed by Felder would be suitable for a small container. However, the compositions of Felder are clearly for use as contrast agents

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and/or other pharmaceutical use and such compositions are mainly contained in vials, as specifically disclosed by Felder.

Applicant asserts that the person skilled in the art would focus on the repeated teachings of what is important in Felder and would be motivated to improve those elements.

One skilled in the art would not limit improvements only to the general improvements disclosed in a single reference. All of the teachings in the art would be considered. Also, given the disclosure of Felder of contrast agents and pharmaceuticals in vials, one skilled in the art would be motivated to use improved vials.

Applicant asserts that the improvements in Felder teach away from the present invention.

This is not found persuasive as this is not the standard for a reference to provide a teaching away from an embodiment. One improvement is not a teaching away from other. There is nothing to suggest that one skilled in the art would limit themselves to the specific benefits taught Felder. One skilled in the art would be motivated to consider the art as a whole, looking at any possible benefits which may be in the same field of endeavor or reasonable pertinent to the problem being solved. Clearly, Felder teaches the use of metal complexes which are contained in a vial. This is well known in the art. The secondary references teach that pharmaceuticals, including contrast agents, benefit from being in silica-coated vials.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Felder teaches metal complex contrast agents and pharmaceuticals that are in vials. The secondary references teach that vials that are coated with silica are advantageous as containers for contrast agents and/or pharmaceuticals. Thus, the references are in the same field of endeavor (diagnostic pharmaceuticals) and/or reasonably pertinent to the problem being solved, forming vials of pharmaceutical agents. Clearly, the use of silica coated vials in a known advantage in the field of pharmaceuticals, and therefore one skilled in the art would have been

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motivated to obtain these benefits for various pharmaceuticals/contrast agents, such as, those disclosed by Felder. Therefore, the motivation to combine arises from the benefits of the prior art.

Applicant asserts that there is no teaching in Felder of leaching problems and this is the benefit set forth in DE '958.

The primary reference does not need to state a specific problem in the reference for an improvement in the art to be obvious. The leaching problem is taught in the art, by DE '958, that various pharmaceuticals and diagnostic agents suffer from leaching and that problem can be prevented by using silica coated vials. Clearly, one skilled in the art would see that the benefit would hold true for various pharmaceuticals and diagnostic agents, as taught by DE '958, such as, the pharmaceutical/diagnostic agents disclosed by Felder.

Applicant asserts that Walther is silent on vials, but only recites hollow glass bodies.

This is not persuasive as there is no clear delineation between a vial and a bottle of glass body or container. These terms seem interchangeable and clearly, given its broadest reasonable interpretation, a vial, as claimed, would encompass a bottle, especially since they are for the same use as a container for a pharmaceutical. It is noted that the term vial is defined as a small container. Clearly the glass bodies disclosed by Walther are containers and are relatively small for containing a pharmaceutical agent.

Applicant also asserts that Walther does not limit the coating to silicon, but teaches a few possibilities and there is nothing to point to silicon.

This is not found persuasive because Walther only teaches three possibilities (or mixtures thereof), and one skilled in the art would clearly envisage the use of SiO₂ from this very limited number of possibilities shown in the abstract, as well as, the claims.

Claims 1, 5, 6, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albert (US 5,545,396) in view of either one of Schott Glaswerke (DE 29609958) or Walther (US 6,200,658), for the reasons set forth in the office action mailed 6/29/2004.

Applicant's arguments filed 9/30/2004 have been fully considered but they are not persuasive.

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Applicant asserts that Albert discloses a coating on a glass vessel to reduce relaxation of the gas on the walls and since Albert teaches silicon to solve a problem, which is different from silica, then Albert teaches away from the claimed invention.

This is not found persuasive because this is taken out of context in the invention of Albert. Albert uses the siliconized tubes in phantoms, e.g., in vitro test to check its ability as a contrast agent. The container used herein is for testing the ability of the hyperpolarized gas as a contrast agent. The improvement in the art is taught as storing the pharmaceutical agent. Albert does not teach storage of the diagnostic agent in siliconized vials, but teaches storage of the diagnostic agent in glass vials, see example 3. Further, one improvement in the art, does not provide a teaching away from another. A teaching away is provided when the art actually teaching a negative aspect is obtained by a certain modification. Nowhere in the cited art is any negative teaching (a teaching away) from the use of silica coated vials for storage of pharmaceuticals, rather only positive teachings are seen in the cited art. Also, applicant's assertion that "silicon" defines a carbon containing polymer which is not the same as silica is a somewhat vague argument. Silicon is an element, Si, which is not found naturally, but obtained by naturally occurring silica.

Claims 1, 5 and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ardenkjaer-Larsen (US 6,466,814) in view of either one of Schott Glaswerke (DE 29609958) or Walther (US 6,200,658),), for the reasons set forth in the office action mailed 6/29/2004.

Applicant's arguments filed 9/30/2004 have been fully considered but they are not persuasive.

Applicant asserts that Ardenkjaer-Larsen does not disclose vials because the recitation of, "containers which contain a plurality of thin wall tubes of thin walled quartz, glass or plastic," and syringes and ampoules do not correspond to vials.

This is not found persuasive because the term vial is defined as any small container. Such is disclosed by Ardenkjaer-Larsen. Vials are not limited to being made of glass or any specific material. Vials may be made of quartz, glass, plastic or other materials. It is also noted that quartz itself is silica. Further, it is the secondary references that teach various advantages of using silica-coated vials for

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storage of pharmaceuticals and diagnostic agents. Thus, one skilled in the art would have been motivated to employ such coated vials for other known pharmaceuticals.

Conclusion

No claims are allowed at this time.

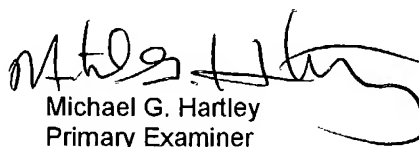
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (571) 272-0616. The examiner can normally be reached on M-Tu and Th-F, 7:30-4, Telework on Wed..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael G. Hartley
Primary Examiner
Art Unit 1616

11/5/2004